(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 404 233 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
02.12.2009 Bulletin 2009/49

(21) Application number: **02742123.9**

(22) Date of filing: **12.06.2002**

(51) Int Cl.:
A61B 17/14 *(2006.01)* ***A61B 5/15*** *(2006.01)*

(86) International application number:
PCT/US2002/019053

(87) International publication number:
WO 2002/100251 (19.12.2002 Gazette 2002/51)

(54) **SELF OPTIMIZING LANCING DEVICE WITH ADAPTATION MEANS TO TEMPORAL VARIATIONS IN CUTANEOUS PROPERTIES**

SELBSTOPTIMIERENDE LANZETTENVORRICHTUNG MIT ADAPTATIONSMITTEL FÜR ZEITLICHE SCHWANKUNGEN VON HAUTEIGENSCHAFTEN

AUTOPIQUEUR A OPTIMISATION AUTOMATIQUE PRESENTANT DES MOYENS D'ADAPTATION AUX VARIATIONS TEMPORELLES DES PROPRIETES CUTANEES

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR
Designated Extension States:
SI

(30) Priority: **12.06.2001 US 298001 P**

(43) Date of publication of application:
07.04.2004 Bulletin 2004/15

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EP 1 404 233 B1

Printed by Jouve, 75001 PARIS (FR)

Description

TECHNICAL FIELD

[0001] Lancing devices are well known in the medical health-care products industry for piercing the skin to produce blood for analysis. Biochemical analysis of blood samples is a diagnostic tool for determining clinical information. Many point-of-care tests are performed using capillary whole blood, the most common being monitoring diabetic blood glucose level. Other uses for this method include the analysis of coagulation based on Prothrombin time measurement. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

BACKGROUND ART

[0002] Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancet drivers that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to actuate the lancet. Typically, the device is pre-cocked, or the user cocks the device. The device is held against the skin and the user, or pressure from the users skin, mechanically triggers the ballistic launch of the lancet. The forward movement, and depth of skin penetration of the lancet is determined by a mechanical stop and/or damping, as well as a spring or cam which retract the lancet.

[0003] Current devices generally rely on adjustable mechanical stops or damping to control the lancet's depth of penetration to compensate for skin thickness and hydration.

[0004] Such devices have the possibility of multiple strikes due to recoil, in addition to vibratory stimulation of the severed nerves as the driver impacts the end of the launcher stop. Cams may offer rough control of lancet velocity in and out of the skin, but do not allow for compensation for skin thickness and hydration. Variations in skin thickness and hydration may yield different results in terms of pain perception, blood yield and success of obtaining blood from different users of the lancing device.

[0005] GB 2,335990 describes an apparatus having a shaft that can sense the depth of penetration, for penetrating into a substrate having an impedance that varies according to the depth under a surface of the substrate. The shaft has a tip for penetration and has conductive ends near to the tip of the shaft. A change of impedance of material between the conductive ends can be sensed to provide information on the depth of penetration.

[0006] US 6,171,325 describes a multi-shaft apparatus for incising a substrate of soft resilient material such as a body tissue. The incising apparatus includes two or more incision shafts each having a distal edge. The shafts are not affixed to each other and are allowed to slide against each other to drive the distal edges alternately against the substrate to incise the substrate.

[0007] EP 1,101,443 describes the use of a substantially free-standing voice coil within a lancing device in coordination and combination with a stationary magnet and electronic circuit in a lancing device. When the electronic lancing device is initiated by a user, the voltage source within the electronic lancing device provides sufficient current through the voice coil such that the coil and lancet are repulsed from the magnet and propelled into the puncture site. The voltage source subsequently reverses the current through the voice coil to supply sufficient attractive current through the voice coil such that the lancet is retracted.

DISCLOSURE OF INVENTION

[0008] The invention is defined in the claims.

[0009] Embodiments of the present invention are related to medical health-care products and to methods for obtaining body fluids for chemical analysis. More particularly, embodiments of the invention relate to devices and methods for piercing the skin (lancing) using an electrically driven lancet having user definable lancet parameters such as lancet displacement, velocity of incision, retraction, acceleration, and tissue dwell time. A device having features of the invention can compensate for long-term changes in skin physiology, nerve function, and peripheral vascular perfusion such as occurs in diabetes, as well as diurnal variation in skin tensile properties. Alternatively, a device having features of the invention can compensate for skin differences between widely differing populations such as pediatric and geriatric patients.

[0010] An embodiment of the invention is directed to a lancing device which controls the advancement and retraction of a lancet by monitoring the position of the lancet in conjunction with a control feedback for modulating the lancet driver to follow a predetermined profile.

BRIEF DESCRIPTION OF DRAWING

[0011] The objects, advantages and features of this invention will be more readily appreciated from the following detailed description, when read in conjunction with the accompanying drawing, in which: Figures 1A and 2A illustrate the displacement over time profile of a harmonic spring/mass system and a controlled lancet.

Figures 1B and 2B illustrate the velocity over time profiles of a harmonic spring/mass system and a controlled lancet

Figure 3 illustrates a controlled actuator using an electromagnetic actuator to drive the lancet.

Figure 4 is a flowchart illustrating a controlled feedback loop.

Figure 5 is a graph of force vs, time during the advancement and retraction of a lancet showing the characteristic phases of the lancing cycle.

BEST MODE FOR CARRYING OUT THE INVENTION

[0012] Lancing device is generally defined to mean any self-contained device for puncturing the skin for the purpose of obtaining a body fluid sample. Lancing devices are typically disposable and reusable in their entirety, or in part. For example, some lancing devices are disposed of as biohazards after one usage. Other lancing devices dispose of only the portions that come in contact with the skin.

[0013] Lancet is generally defined to mean any sharp or blunt member used to puncture the skin for the purpose of cutting blood vessels and allowing blood to flow to the surface of the skin. The lancet has certain parameters such as diameter to define the cross-sectional area of the member, and geometry to define the shape of the distal or front lancing end of the member.

[0014] Lancet driver is generally defined to mean any means for controlling the advancement and retraction of the lancet. Examples of lancet drivers can include spring actuated drivers, electromagnetic drivers and piezoelectric drivers. Examples of electromagnetic drivers include solenoids, linear induction motors, and linear reluctance motors.

[0015] Feedback loop is generally defined to mean a feedback control loop where information is collected about the current behavior of the lancet (such as relative lancet position, rate and direction of lancet motion, resistance to lancet motion, etc.) and is used to modulate the drive power applied to the lancet.

[0016] Processor is generally defined to mean a high-speed digital processor containing memory and calculation capabilities. Such processor is used to modulate the lancet driver. Modulate is generally defined to mean controlling the profile of the lancet.

[0017] Profile is generally defined to mean a displacement, velocity or acceleration versus time plot or table.

[0018] Typically, the lancet and the lancet driver are configured so that lancet velocity is high at the moment of first contact with the skin, decelerates to zero at the predetermined penetration depth, and immediately retracts from the skin, leaving at approximately the same velocity that it entered. The energy required for lancet actuation is initially stored as potential energy, as in the actuators discussed above. During the lancing cycle, the stored energy is transferred into the kinetic energy of the lancet, which is then transferred to potential energy at the apex of the trajectory, and is immediately transferred back into kinetic energy by the retraction mechanism. The actuation and retraction velocities are similar, though opposite in sign. The devices which employ spring or cam driving methods have a symmetrical actuation displacement and velocity profile on the advancement and retraction of the lancet. In most of the available lancet devices, once the launch is initiated, the stored energy determines the velocity profile until the energy is dissipated. Piezoelectric assisted cutting methods have also been described; however, the launching mechanism is spring driven, and no feedback is described for controlling lancet motion. Variations in skin properties require controlling impact, retraction velocity, and dwell time of the lancet within the tissue.

[0019] Advantages are achieved by taking into account that tissue dwell time is related to the amount of skin deformation as the lancet tries to puncture the surface of the skin and variance in skin deformation from patient to patient based on skin hydration with regard to dwell time and the necessity to achieve at least 100 microns of skin depth to successfully sample blood.

[0020] Pain reduction can be achieved through both the rapid lancet cutting speed and light weight of the proposed lancet. The rapid cutting minimizes the shock waves produced when the lancet strikes the skin in addition to compressing the skin for efficient cutting. Due to the very light mass of the lancet and lack of mechanical stop, there is insubstantial or no vibrational energy transferred to the finger during cutting.

[0021] Lancing devices such as the spring and cam driven devices typically yield 7080 % success rate in obtaining a blood droplet, as some lancing events are unsuccessful. Success rate is dependent on reaching the blood capillaries and venuoles, which yield the blood sample. Due to variation in skin thickness and hydration, some skin will deform more before cutting starts, and hence the actual depth of penetration will be less, resulting in less capillaries and venuoles cut. An electronic feedback mechanism yields accurate measurement of skin resistance, and therefore depth of penetration and thus directly improves the success rate of blood yield.

[0022] Spontaneous blood yield occurs when blood from the cut vessels flows up the wound tract to the surface of the skin, where it can be collected and tested. Tissue elasticity parameters may force the wound tract to close behind the retracting lancet preventing the blood from reaching the surface. If however, the lancet were to dwell before being retracted, and or be withdrawn slowly from the wound tract, thus keeping the wound open, blood could flow up the patent channel, as described in a copending application WO/2002/00461.

[0023] The ability to control the lancet speed into and out of the wound is critical as it allows the device to compensate for changes in skin thickness and variations in skin hydration to achieve spontaneous blood yield with maximum success rate while minimizing pain. This is done by taking into consideration the skin deformation to achieve a desirable tissue dwell time and depth of penetration.

[0024] This ability to control velocity and depth of penetration therefore requires an actuation mechanism where feedback is an integral part of driver control. An example of such a driver is the electromagnetic actuator design as described in a copending application US 2004-0083686. Such drivers can control either metal or polymeric lancets. The dynamic control of such a driver is shown in Figure 2A which illustrates the controlled displacement profile and Figure 2B which illustrates the con-

trolled velocity profile. These are compared to Figures 1A and 1B which illustrate the displacement and velocity profiles, respectively, of a harmonic spring/mass system.

[0025] It is, accordingly, an advantage to control the lancet displacement, velocity, and acceleration at several steps in the lancing cycle. Such control increases the success rate of obtaining an acceptable sample volume of blood and the ability to obtain a spontaneous blood sample, and decreases the pain perceived by the patient during the lancing procedure. Reduced pain is achieved because of fast entry of the lancet into the tissue. Reduced lancet velocity with increased lancet dwell time in the tissue at a point where the lancet intersects the venuoles and capillary mesh, allows the blood to pool, promoting uninhibited flow into the exit channel. Retraction of the lancet at a low velocity following the sectioning of the venuole/capillary mesh allows the blood to flood the wound tract and flow freely to the surface, thus using the lancet to keep the channel open during retraction. Low-velocity retraction of the lancet near the wound flap prevents the wound flap from sealing off the channel. Thus, the ability to slow the lancet retraction directly contributes to increasing the success rate of obtaining blood. Increasing the sampling success rate to near 100% is considered an essential prerequisite to combine sampling and acquisition into an integrated sampling module (e.g. an integrated glucose sampling module which incorporates a glucose test strip).

[0026] Reference will now be made to exemplary embodiments of the invention. In the first embodiment, a lancing device contains a lancet and lancet driver. The lancet and lancet driver are configured so that feedback control is based on lancet displacement, velocity, or acceleration. The feedback control information relating to the actual lancet path is returned to a processor that regulates the energy to the lancet driver, thereby precisely controlling the lancet throughout its advancement and retraction. The lancet driver may be driven by electric current which includes direct current and alternating current. Figure 3 shows an electromagnetic type lancet driver that is capable of driving an iron core mounted to the lancet assembly using a direct current (DC) power supply. The solenoid is divided into three separate coils along the path of the lancet, two end coils and a middle coil. Direct current is applied to the coils to advance and retract the lancet. The coils are used in pairs to draw the iron core into the solenoid. As one of the drive coils is switched on, the corresponding induced current in the adjacent coil is monitored. The strength of this induced current is related to the degree of magnetic coupling provided by the iron core, and can be used to infer the position of the core. After a period of time, the drive voltage is turned off, allowing the coils to relax, and then the cycle is repeated. The degree of magnetic coupling between the coils is converted electronically to a proportional DC voltage that is supplied to an analog-to-digital converter. The digitized position signal is then processed and compared to a desired "nominal" position by a central processing unit (CPU). Error between the actual and nominal positions is used by the CPU to set the level and/or length of the next power pulse to the solenoid coils.

[0027] Referring to FIG. 3, the stationary housing (40) contains the solenoid whose first coil (52) is separated by a magnetically permeable spacer (50) from the adjacent coil. The housing (40) is made from a magnetically permeable material, and a magnetically permeable spacer is assembled outside of the first coil. The spacers and housing form a magnetic circuit that focuses the magnetic field produced by the coil between the inner diameter edges of the spacers. The same is true of each of the other coils, the housing, and their spacers. The inner guide tube (48) isolates the lancet (42) and iron core (46) from the solenoid coils (52). The lancet (42) and iron core (46) are centered by the lancet guide (44). The lancet (42) is advanced and retracted by alternating the current between the first coil (52), the middle coil (not shown), and the third coil (not shown), singly or in combination, to advance or retract the iron core (46). The lancet guide (44) also serves as a stop for the iron core (46) mounted to the lancet (42).

[0028] In another embodiment, the solenoid comprises three coils consisting of a central driving coil flanked by balanced detection coils built into the driver assembly so that they surround the actuation region with the region centered on the middle coil at mid-stroke. When a current pulse is applied to the central coil, voltages are induced in the adjacent sense coils. If the sense coils are connected together so that their induced voltages oppose each other, the resulting signal will be positive for deflection from mid-stroke in one direction, negative in the other direction, and zero at mid-stroke. This measuring technique is commonly used in Linear Variable Differential Transformers (LVDT). Lancet position is determined by measuring the electrical balance between the two sensing coils.

[0029] In another embodiment, the feedback loop uses a commercially available LED/photo transducer module such as the OPB703 (manufactured by Optek Technology, Inc., 1215 W. Crosby Road, Carrollton, Texas, 75006 (972) 323-2200) to determine the distance from the fixed module on the stationary housing to a reflective surface or target mounted on the lancet assembly. The LED acts as a light emitter to send light beams to the reflective surface which in turn reflects the light back to the photo transducer which acts as a light sensor. Distances over the range of 4mm or so are determined by measuring the intensity of the reflected light by the photo transducer.

[0030] In another embodiment, the feed-back loop uses a magnetically permeable region on the lancet shaft itself as the core of a Linear Variable Differential Transformer (LVDT). A permeable region created by selectively annealing a portion of the lancet shaft, or by including a component in the lancet assembly, such as ferrite, with sufficient magnetic permeability to allow coupling between adjacent sensing coils. Coil size, number of wind-

ings, drive current, signal amplification, and air gap to the permeable region are specified in the design process.

[0031] In another embodiment, the feedback control supplies a piezoelectric driver, superimposing a high frequency oscillation on the basic displacement profile. The piezoelectric driver provides improved cutting efficiency and reduces pain by allowing the lancet to "saw" its way into the tissue or to destroy cells with cavitation energy generated by the high frequency of vibration of the advancing edge of the lancet. The drive power to the piezoelectric driver is monitored for an impedance shift as the device interacts with the target tissue. The resulting force measurement, coupled with the known mass of the lancet is used to determine lancet acceleration, velocity, and position.

[0032] Figure 4 shows the operation of the feedback loop using the processor. The processor (60) stores profiles (62) in non-volatile memory. A user inputs information (64) about the desired circumstances for the lancing event. The processor (60) selects a profile (62) from a set of alternative profiles that have been preprogrammed in the processor (60) based on typical device performance determined through testing at the factory. The processor (60) may customize by either scaling or modifying the profile based on additional user input information (64). Once the processor has chosen and customized the profile, the processor (60) is ready to modulate the power from the power supply (66) to the lancet driver (68) through an amplifier (70). The processor (60) measures the location of the lancet (72) using a position sensing mechanism (74) through an analog to digital converter (76). Examples of position sensing mechanisms have been described in the embodiments above. The processor (60) calculates the movement of the lancet by comparing the actual profile of the lancet to the predetermined profile. The processor (60) modulates the power to the lancet driver (68) through a signal generator (78), which controls the amplifier (70) so that the actual profile of the lancet does not exceed the predetermined profile by more than a preset error limit. The error limit is the accuracy in the control of the lancet.

[0033] After the lancing event, the processor (60) allows the user to rank the results of the lancing event. The processor (60) stores these results and constructs a database (80) for the individual user. Using the database (80), the processor (60) calculates the profile traits such as degree of painlessness, success rate, and blood volume for various profiles (62) depending on user input information (64) to optimize the profile to the individual user for subsequent lancing cycles. These profile traits depend on the characteristic phases of lancet advancement and retraction. The processor (60) uses these calculations to optimize profiles (62) for each user. In addition to user input information (64), an internal clock allows storage in the database (80) of information such as the time of day to generate a time stamp for the lancing event and the time between lancing events to anticipate the user's diurnal needs. The database stores information and statistics for each user and each profile that particular user uses.

[0034] In addition to varying the profiles, the processor calculates the appropriate lancet diameter and geometry necessary to realize the blood volume required by the user. For example, if the user requires a 1-5 microliter volume of blood, the processor selects a 200 micrometer lancet diameter to achieve these results. For each class of lancet, both diameter and lancet tip geometry, is stored in the processor to correspond with upper and lower limits of attainable blood volume based on the predetermined displacement and velocity profiles.

[0035] The lancing device is capable of prompting the user for information at the beginning and the end of the lancing event to more adequately suit the user. The goal is to either change to a different profile or modify an existing profile. Once the profile is set, the force driving the lancet is varied during advancement and retraction to follow the profile. The method of lancing using the lancing device comprises selecting a profile, lancing, determining lancing profile traits for each characteristic phase of the lancing cycle, and optimizing for subsequent lancing events.

[0036] Figure 5 shows the characteristic phases of lancet advancement and retraction on a graph of force versus time illustrating the force exerted by the lancet driver on the lancet to achieve the desired displacement and velocity profile. The characteristic phases are the lancet introduction phase A-C where the lancet is longitudinally advanced into the skin, the lancet rest phase D where the lancet terminates its longitudinal movement reaching its maximum depth and becoming relatively stationary, and the lancet retraction phase E-G where the lancet is longitudinally retracted out of the skin. The duration of the lancet retraction phase E-G is longer than the duration of the lancet introduction phase A-C, which in turn is longer than the duration of the lancet rest phase D.

[0037] The introduction phase further comprises a lancet launch phase prior to A when the lancet is longitudinally moving through air toward the skin, a tissue contact phase at the beginning of A when the distal end of the lancet makes initial contact with the skin, a tissue deformation phase A when the skin bends depending on its elastic properties which are related to hydration and thickness, a tissue lancing phase which comprises when the lancet hits the inflection point on the skin and begins to cut the skin B and the lancet continues cutting the skin C. The lancet rest phase D is the limit of the penetration of the lancet into the skin. Pain is reduced by minimizing the duration of the lancet introduction phase A-C so that there is a fast incision to a certain penetration depth regardless of the duration of the deformation phase A and inflection point cutting B which will vary from user to user. Success rate is increased by measuring the exact depth of penetration from inflection point B to the limit of penetration in the lancet rest phase D. This measurement allows the lancet to always, or at least reliably, hit the capillary beds which are a known distance underneath

the surface of the skin.

[0038] The lancet retraction phase further comprises a primary retraction phase E when the skin pushes the lancet out of the wound tract, a secondary retraction phase F when the lancet starts to become dislodged and pulls in the opposite direction of the skin, and lancet exit phase G when the lancet becomes free of the skin. Primary retraction is the result of exerting a decreasing force to pull the lancet out of the skin as the lancet pulls away from the finger. Secondary retraction is the result of exerting a force in the opposite direction to dislodge the lancet. Control is necessary to keep the wound tract open as blood flows up the wound tract. Blood volume is increased by using a uniform velocity to retract the lancet during the lancet retraction phase E-G regardless of the force required for the primary retraction phase E or secondary retraction phase F, either of which may vary from user to user depending on the properties of the user's skin.

[0039] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein.

[0040] It is intended that the specification and examples be considered as exemplary only.

Claims

1. A lancing device comprising:

   a lancet (54) comprising a shaft having a proximal driving end and a distal lancing end;
   a lancet driver (52) coupled to said lancet for longitudinal displacement of said lancet;
   a lancet postion sensing mechanism (74) and
   a lancet controller (60) coupled to said lancet driver and said lancet position sensing mechanism, said lancet controller being operable to measure the location of the lancet (72) using the position sensing mechanism (74) and to calculate the movement of the lancet, said lancet controller comprising a feedback loop for monitoring the longitudinal displacement of said lancet and for modulating the lancet driver to provide a predetermined tissue lancing profile in terms of a displacement, velocity or acceleration versus time having characteristic phases for lancet advancement and retraction.

2. A lancing device according to claim 1 wherein:

   said lancet driver comprises a solenoid.

3. A lancing device according to claim 2 wherein;

   said solenoid drives the lancet with electric current.

4. A lancing device according to claim 3 wherein:

   said lancet controller comprises additional coil segments disposed adjacent to said solenoid for monitoring the lancet displacement.

5. A lancing device according to claim 1 wherein:

   said lancet driver comprises a means for oscillating the lancet to improve the lancet cutting ability.

6. A lancing device according to claim 5 wherein:

   said oscillating means comprises a piezoelectric driver.

7. A lancing device according to claim 6 wherein:

   said lancet controller controllably varies said tissue lancing profile as a function of impedance changes sensed from said piezoelectric driver resulting from said lancet interacting with said tissue.

8. A lancing device according to claim 5 wherein:

   said lancet controller comprises a means for sensing a change in lancing pressure to determine the lancet displacement.

9. A lancing device according to any one of the preceding claims wherein:

   said lancet controller comprises a processor for modulating the lancet driver.

10. A lancing device according to claim 9 wherein:

    said processor comprises memory for storage and retrieval of a set of alternative lancing profiles which the processor uses to modulate the lancet driver.

11. A lancing device according to claim 10 wherein:

    a user of said lancing device selects the profile desired from said set of alternative profiles to modulate the lancet.

12. A lancing device according to any one of claims 9 to 11 wherein:

    said processor optimizes said phases of said tissue lancing profile based on information entered by the user of said lancing device.

13. A lancing device according to any one of claims 9 to

12 wherein:

said processor modulates the lancet driver by comparing an actual profile of the lancet to the profile and maintaining a preset error limit between the actual profile and the profile.

14. A lancing device according to any one of claims 9 to 13 wherein:

said processor comprises a database for the user.

15. A lancing device according to claim 14 wherein:

said database allows the calculation of statistics for a profile.

16. A lancing device according to any one of claims 9 to 15 wherein:

said processor comprises an internal clock which links the lancing event with a time stamp.

17. A lancing device according to any one of claims 9 to 16 wherein:

said processor calculates an appropriate lancet diameter and geometry to collect a blood volume required by the user.

18. A lancing device according to any one of claims 1 to 17 wherein:

said position sensing mechanism comprises a light detecting sensor and a light emitter for monitoring the relative position of said lancet, said lancet further comprising a reflective surface on said proximal end such that said light emitter emits light such that said light is reflected from said reflective surface to said sensor.

19. A lancing device according to any one of claims 1 to 17 wherein:

said position sensing mechanism comprises an electromagnetic sensor for monitoring the relative position of at least one magnetically permeable region disposed on a region of said shaft, said sensor comprising at least one solenoid.

Patentansprüche

1. Lanzetten- bzw. Stechhilfenvorrichtung, die aufweist:

eine Lanzette (54) mit einem Schaft, welcher ein proximales Antriebsende und ein distales Einstechende hat,
einen Lanzettenantrieb (52), der mit der Lanzette gekoppelt ist, um die Lanzette in Längsrichtung zu verlagern,
einen Erfassungsmechanismus (74) für die Lanzettenposition und
eine Lanzettensteuerung (60), die mit dem Lanzettenantrieb und dem Erfassungsmechanismus für die Lanzettenposition gekoppelt ist, wobei die Lanzettensteuerung so betreibbar ist, daß sie die Position der Lanzette (72) unter Verwendung des Positionserfassungsmechanismus' (74) mißt und die Bewegung der Lanzette berechnet, wobei die Lanzettensteuerung eine Rückkopplungsschleife aufweist für das Überwachen der Verlagerung der Lanzette in Längsrichtung und für das Modulieren des Lanzettenantriebs derart, daß ein vorbestimmtes Gewebeeinstechprofil im Hinblick auf eine Verlagerung, eine Geschwindigkeit oder einer Beschleunigung gegenüber der Zeit bereitgestellt wird, welches charakteristische Phasen für das Vorwärtsbewegen bzw. Vorschieben und das Zurückziehen der Lanzette hat.

2. Lanzettenvorrichtung nach Anspruch 1, wobei:

der Lanzettenantrieb ein Solenoid aufweist.

3. Lanzettenvorrichtung nach Anspruch 2, wobei:

das Solenoid die Lanzette mit elektrischem Strom antreibt.

4. Lanzettenvorrichtung nach Anspruch 3, wobei:

die Lanzettensteuerung zusätzliche Spulensegmente aufweist, die benachbart zu dem Solenoid angeordnet sind, um die Verlagerung der Lanzette zu überwachen.

5. Lanzettenvorrichtung nach Anspruch 1, wobei:

der Lanzettenantrieb ein Mittel umfaßt, um die Lanzette in Schwingungen zu versetzen und so die Schneidfähigkeit der Lanzette zu verbessern.

6. Lanzettenvorrichtung nach Anspruch 5, wobei:

das Schwingungen erzeugende Mittel einen piezoelektrischen Antrieb aufweist.

7. Lanzettenvorrichtung nach Anspruch 6, wobei:

die Lanzettensteuerung das Gewebeeinstechprofil auf kontrollierbare Weise variiert als eine

Funktion von Impedanzveränderungen, die von dem piezoelektrischen Antrieb erfaßt werden und aus der Wechselwirkung der Lanzette mit dem Gewebe resultieren.

8. Lanzettenvorrichtung nach Anspruch 5, wobei:

die Lanzettensteuerung ein Mittel zum Erfassen einer Veränderung im Einstechdruck aufweist, um die Verlagerung der Lanzette festzustellen.

9. Lanzettenvorrichtung nach einem der vorangegangenen Ansprüche, wobei:

die Lanzettensteuerung einen Prozessor zum Modulieren des Lanzettenantriebs aufweist.

10. Lanzettenvorrichtung nach Anspruch 9, wobei:

der Prozessor eine Speicher für das Speichern und Abrufen eines Satzes von alternativen Einstechprofilen aufweist, welche der Prozessor verwendet, um den Lanzettenantrieb zu modulieren.

11. Lanzettenvorrichtung nach Anspruch 10, wobei:

ein Benutzer der Lanzettenvorrichtung das gewünschte Profil aus dem Satz von alternativen Profilen auswählt, um die Lanzette zu modulieren.

12. Lanzettenvorrichtung nach einem der Ansprüche 9 bis 11, wobei:

der Prozessor die Phasen des Gewebeeinstechprofils auf Basis von durch den Benutzer der Lanzettenvorrichtung eingegebenen Informationen optimiert.

13. Lanzettenvorrichtung nach einem der Ansprüche 9 bis 12, wobei:

der Prozessor den Lanzettenantrieb moduliert, indem er ein tatsächliches Profil der Lanzette mit dem Profil vergleicht und eine zuvor festgelegte Fehlergrenze zwischen dem tatsächlichen Profil und dem Profil einhält.

14. Lanzettenvorrichtung nach einem der Ansprüche 9 bis 13, wobei:

der Prozessor eine Datenbank für den Benutzer aufweist.

15. Lanzettenvorrichtung nach Anspruch 14, wobei:

die Datenbank das Berechnen von Statistiken für ein Profil ermöglicht.

16. Lanzettenvorrichtung nach einem der Ansprüche 9 bis 15, wobei:

der Prozessor einen Taktgeber aufweist, welcher das Einstechereignis mit einem Zeitstempel verknüpft.

17. Lanzettenvorrichtung nach einem der Ansprüche 9 bis 16, wobei:

der Prozessor einen geeigneten Lanzettendurchmesser und eine geeignete Lanzettengeometrie berechnet, um ein von dem Benutzer benötigtes Blutvolumen zu sammeln.

18. Lanzettenvorrichtung nach einem der Ansprüche 1 bis 17, wobei:

der Positionserfassungsmechanismus einen Lichterfassungssensor und einen Lichtemitter aufweist, um die relative Position der Lanzette zu überwachen, wobei die Lanzette weiterhin eine reflektierende Oberfläche an dem proximalen Ende aufweist, so daß der Lichtemitter Licht emittiert und das Licht von der reflektierenden Oberfläche zu dem Sensor reflektiert wird.

19. Lanzettenvorrichtung nach einem der Ansprüche 1 bis 17, wobei:

der Positionserfassungsmechanismus einen elektromagnetischen Sensor aufweist, um die relative Position wenigstens eines magnetisch permeablen Bereichs, der in einem Bereich des Schafts angeordnet ist, zu überwachen, wobei der Sensor wenigstens ein Solenoid aufweist.

Revendications

1. Autopiqueur comprenant :

une lancette (54) comprenant un arbre ayant une extrémité d'entraînement proximale et une extrémité de piquage distale ;
un organe d'entraînement de lancette (52) couplé à ladite lancette pour le déplacement longitudinal de ladite lancette ;
un mécanisme de détection de position de lancette (74) et
un organe de commande de lancette (60) couplé audit organe d'entraînement de lancette et audit mécanisme de détection de position de lancette, ledit organe de commande de lancette étant utilisable pour mesurer l'emplacement de la lancette (72) en utilisant le mécanisme de détection

de position (74) et calculer le mouvement de la lancette, ledit organe de commande de lancette comprenant une boucle de rétroaction pour surveiller le déplacement longitudinal de ladite lancette et pour moduler l'organe d'entraînement de lancette pour fournir un profil de piquage de tissu prédéterminé en termes de déplacement, de vitesse ou d'accélération dans le temps ayant des phases caractéristiques pour l'avancement et la rétraction de la lancette.

2. Autopiqueur selon la revendication 1, dans lequel :

ledit organe d'entraînement de lancette comprend un solénoïde.

3. Autopiqueur selon la revendication 2, dans lequel :

ledit solénoïde entraîne la lancette avec un courant électrique.

4. Autopiqueur selon la revendication 3, dans lequel :

ledit organe de commande de lancette comprend des segments de bobines supplémentaires disposés adjacents au dit solénoïde pour surveiller le déplacement de la lancette.

5. Autopiqueur selon la revendication 1, dans lequel :

ledit organe d'entraînement de lancette comprend un moyen pour faire osciller la lancette pour améliorer la capacité de découpage de la lancette.

6. Autopiqueur selon la revendication 5, dans lequel :

ledit moyen d'oscillation comprend un organe d'entraînement piézo-électrique.

7. Autopiqueur selon la revendication 6, dans lequel :

ledit organe de commande de lancette fait varier de manière contrôlable ledit profil de piquage de tissu en fonction des changements d'impédance détectés à partir dudit organe d'entraînement piézo-électrique découlant de l'interaction de ladite lancette avec ledit tissu.

8. Autopiqueur selon la revendication 5, dans lequel :

ledit organe de commande de lancette comprend un moyen pour détecter un changement de pression de piquage pour déterminer le déplacement de la lancette.

9. Autopiqueur selon l'une quelconque des revendications précédentes, dans lequel :

ledit organe de commande de lancette comprend un processeur pour moduler l'organe d'entraînement de lancette.

10. Autopiqueur selon la revendication 9, dans lequel :

ledit processeur comprend une mémoire pour le stockage et l'extraction d'un ensemble de profils de piquage alternatifs que le processeur utilise pour moduler l'organe d'entraînement de lancette.

11. Autopiqueur selon la revendication 10, dans lequel :

un utilisateur dudit autopiqueur sélectionne le profil souhaité dans ledit ensemble de profils alternatifs pour moduler la lancette.

12. Autopiqueur selon l'une quelconque des revendications 9 à 11, dans lequel :

ledit processeur optimise lesdites phases dudit profil de piquage de tissu sur la base des informations entrées par l'utilisateur dudit autopiqueur.

13. Autopiqueur selon l'une quelconque des revendications 9 à 12, dans lequel :

ledit processeur module l'organe d'entraînement de lancette en comparant un profil réel de la lancette au profil et en maintenant une limite d'erreur préréglée entre le profil réel et le profil.

14. Autopiqueur selon l'une quelconque des revendications 9 à 13, dans lequel :

ledit processeur comprend une base de données pour l'utilisateur.

15. Autopiqueur selon la revendication 14, dans lequel :

ladite base de données permet le calcul de statistiques pour un profil.

16. Autopiqueur selon l'une quelconque des revendications 9 à 15, dans lequel :

ledit processeur comprend une horloge interne qui lie l'événement de piquage à un horodatage.

17. Autopiqueur selon l'une quelconque des revendications 9 à 16, dans lequel :

ledit processeur calcule un diamètre approprié de lancette et une géométrie appropriée de lancette pour recueillir un volume de sang requis par l'utilisateur.

18. Autopiqueur selon l'une quelconque des revendications 9 à 17, dans lequel :

ledit mécanisme de détection de position comprend un capteur de détection de lumière et un émetteur de lumière pour surveiller la position relative de ladite lancette, ladite lancette comprenant en outre une surface réflective sur ladite extrémité proximale de sorte que ledit émetteur de lumière émette de la lumière de manière à ce que ladite lumière soit réfléchie de ladite surface réflective vers ledit capteur.

19. Autopiqueur selon l'une quelconque des revendications 1 à 17, dans lequel :

ledit mécanisme de détection de position comprend un capteur électromagnétique pour surveiller la position relative d'au moins une région magnétiquement perméable disposée sur une région dudit arbre, ledit capteur comprenant au moins un solénoïde.

Figure 1A

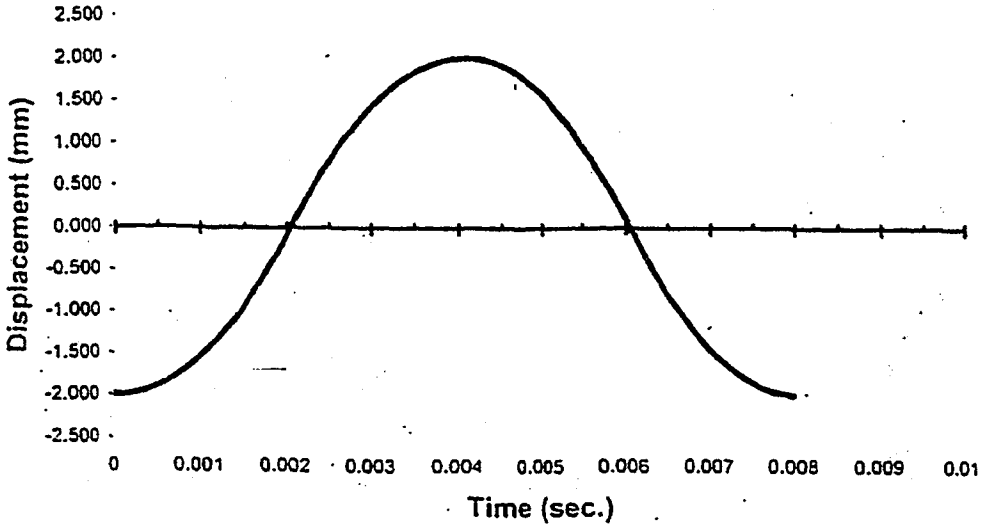

2.500
2.000
1.500
1.000
0.500
0.000
-0.500
-1.000
-1.500
-2.000
-2.500
Displacement (mm)
0
0.001
0.002
0.003
0.004
0.005
0.006
0.007
0.008
0.009
0.01
Time (sec.)

Figure 1B

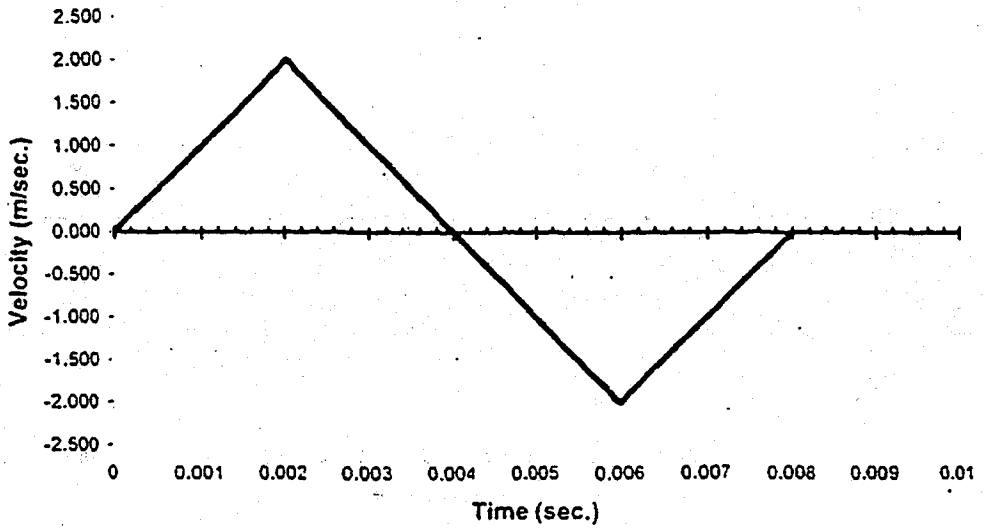

2.500
2.000
1.500
1.000
0.500
0.000
-0.500
-1.000
-1.500
-2.000
-2.500
Velocity (m/sec.)
0
0.001
0.002
0.003
0.004
0.005
0.006
0.007
0.008
0.009
0.01
Time (sec.)

Figure 2A

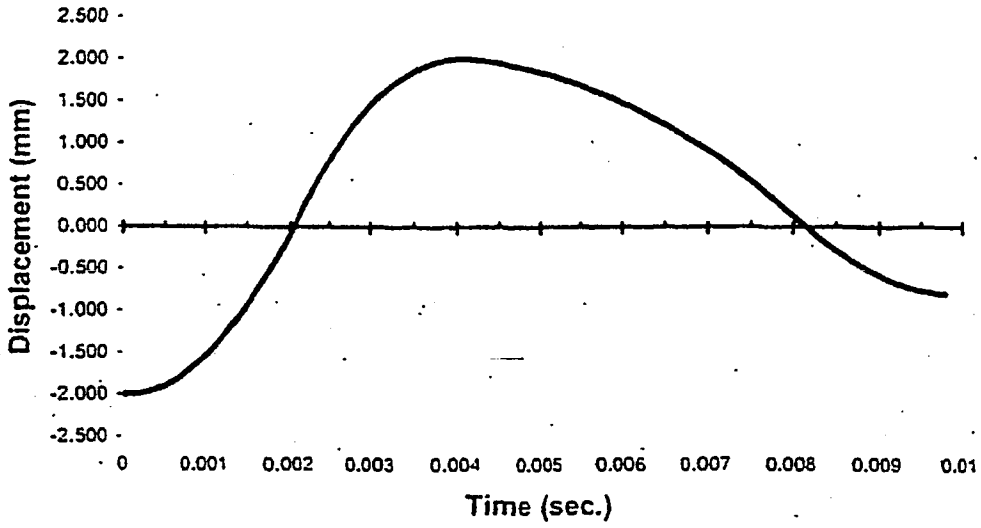
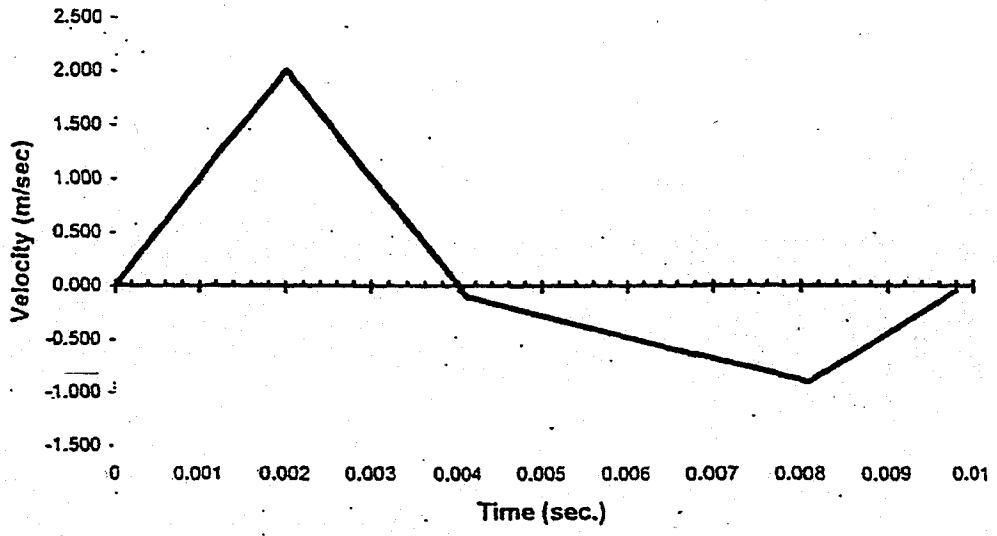

2.500
2.000
1.500
1.000
0.500
0.000
-0.500
-1.000
-1.500
-2.000
-2.500
Displacement (mm)
0
0.001
0.002
0.003
0.004
0.005
0.006
0.007
0.008
0.009
0.01
Time (sec.)

Figure 2B


2.500
2.000
1.500
1.000
0.500
0.000
-0.500
-1.000
-1.500
Velocity (m/sec)
0
0.001
0.002
0.003
0.004
0.005
0.006
0.007
0.008
0.009
0.01
Time (sec.)

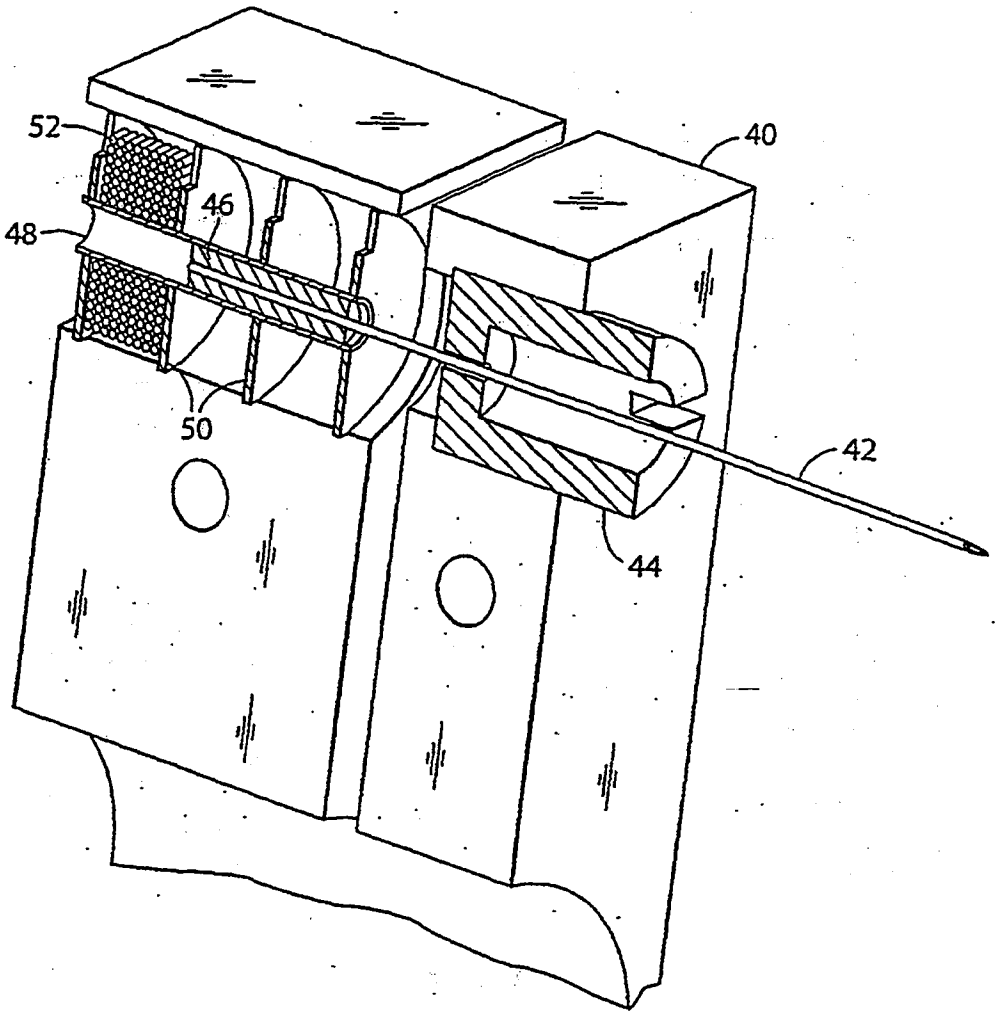


Figure 3

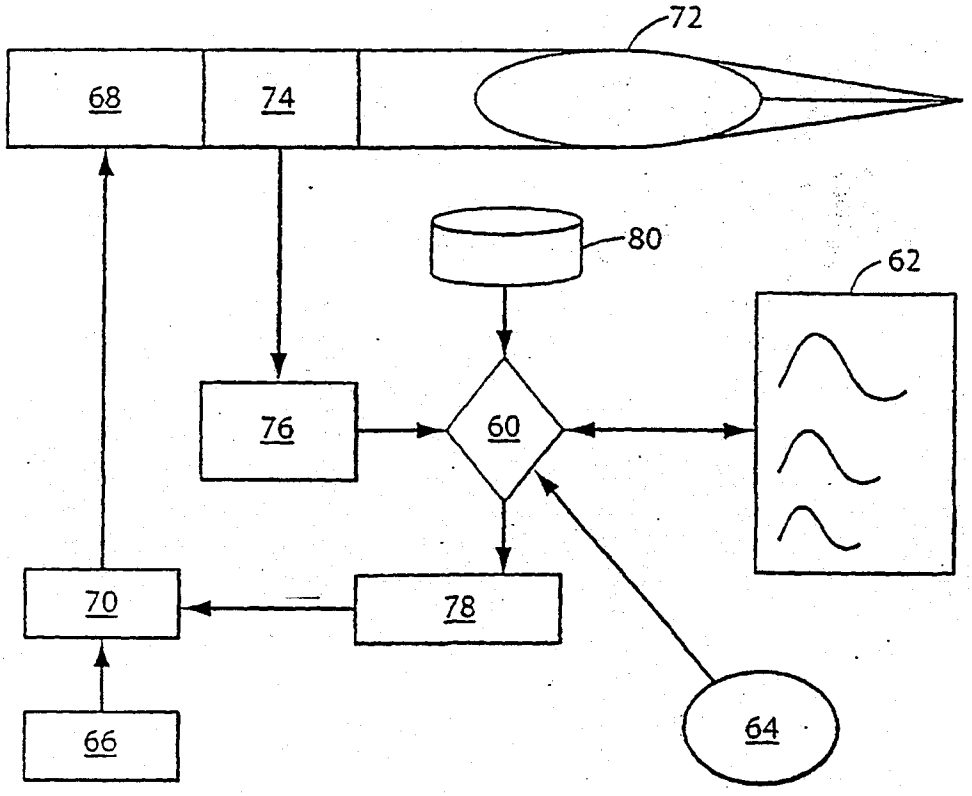


Figure 4

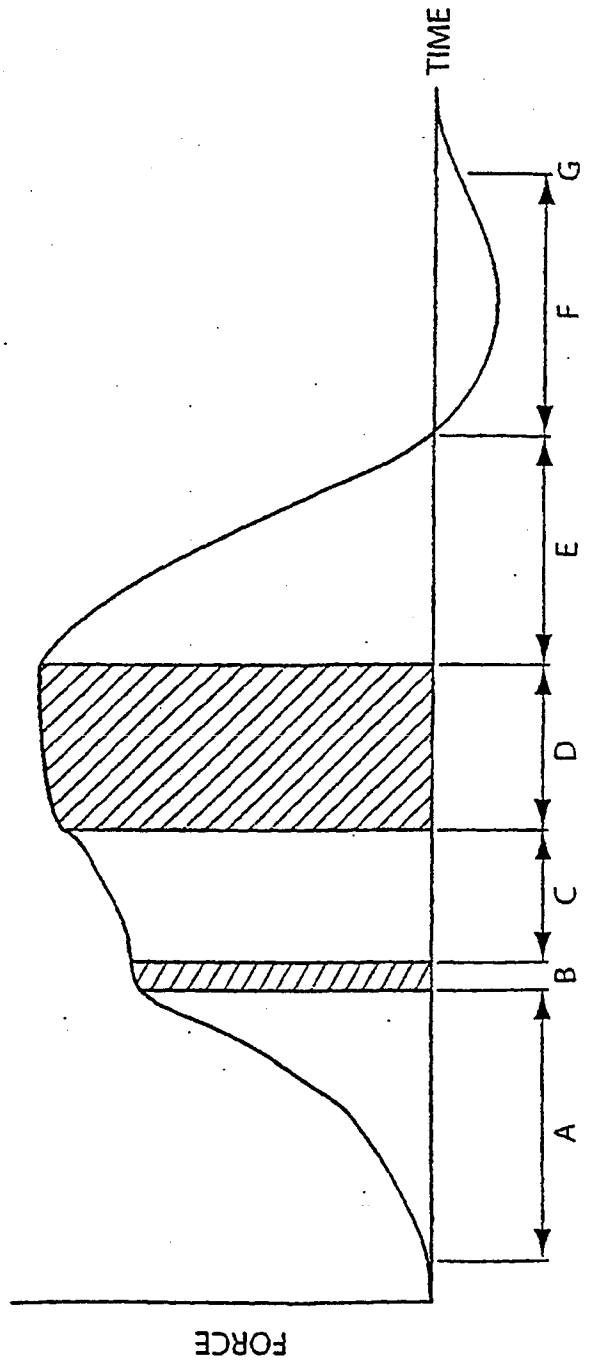


Figure 5

REFERENCES CITED IN THE DESCRIPTION

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